Environmental Investigation of *Salmonella* Enteritidis Phage Type 9c Outbreak Associated with Consumption of Raw Almonds

Investigators: James Sigl (FDB), Mary Palumbo (FDB), Minh Huynh (FDB), and Natalie Hunt-Barta (FDB)

Dates of investigation: May 14 to August 3, 2004

Background

On May 13, 2004 Oregon Public Health Services notified the California Department of Health Services (CDHS) of a cluster of five *Salmonella* ser. Enteritidis (SE) illnesses matched by two-enzyme (Xba1 and Bln1) pulsed field gel electrophoresis (PFGE). These five cases all reported consumption of Kirkland Signature brand raw almonds in the week preceding illness onset. The binomial probability of this history occurring by chance was less than 0.001 using the assumption that 20 percent of Oregon residents consume Kirkland Signature brand almonds each week (survey data indicated nine percent of Oregon residents ate almonds from any source in the preceding week). SE PFGE patterns in PulseNet were reviewed and additional cases were identified. The most recent totals include forty-seven patients in Alaska, Arizona, California, Connecticut, Idaho, Kentucky, Massachusetts, Michigan, Montana, New Mexico, Oregon, Pennsylvania, Tennessee, Utah, Washington, and Saskatchewan. Twenty-nine isolates were phage typed and confirmed as Phage Type 9c (PT9c), twenty of which were from patients with a history of almond consumption and one from a patient who reported no almond consumption (information was not available for eight patients). Eleven cases were hospitalized, and there was one death. Onset dates ranged from January 13, 2002 through April 17, 2004.

Summary: Almonds purchased at Costco warehouses in the northwestern United States were linked to illnesses caused by SE PT9c in early 2004. Traceback investigation revealed that these almonds were processed by Paramount Farms, a California almond grower and processor that sells almonds under a variety of labels and in bulk. Investigation at Paramount did not reveal a source of the outbreak strain of *Salmonella* [redacted] As the investigation progressed, additional case patients were identified, some of whom had not purchased almonds at Costco. The almond consumption history of one case patient in Tennessee was of particular interest as there was no obvious link to Paramount almonds. During 2003-2004, approximately five percent of the almonds that Paramount processed and sold were purchased from outside sources. Traceback of the Tennessee case patient's almond purchases was compared to the traceback of the almonds purchased by Paramount Farms and revealed one common handler and three common huller shellers. Environmental sampling conducted as part of the Tennessee traceback did not reveal the outbreak strain of *Salmonella*. Several other *Salmonella* serotypes were detected. Raw almonds should be considered a potential source of *Salmonella* during epidemiological investigations.

Industry data has confirmed a low level of *Salmonella* contamination in raw almonds. Because of current harvesting and processing practices, reduction or elimination of *Salmonella* in this product may not be feasible without an additional treatment such as heat. The almond industry should implement steps to decrease the risk of illness from this product. Consumers at risk for severe morbidity should avoid consumption of raw almonds.

Paramount Farms, Inc.
13646 Highway 33, Lost Hills, CA 93249-9719 Phone (661) 797-6500
Contacts: Dave Szeflin – Vice President of Operations
Hiroki Hiura – Quality Assurance Manager
Brian Ezell – Managing Director Almond Division
Alex Alaniz – Director of Almond Operations
Curtis Hudson – Vice President of Logistics

Traceback Investigation: Initial illnesses reported by Oregon were epidemiologically linked to consumption of Kirkland Signature brand raw almonds, packed by Paramount Farms and purchased at Costco warehouse stores. In 2003-2004, approximately five percent of the shelled almonds received at the Paramount processing plant were purchased and commingled with PHS almonds. These outside suppliers were listed on the traceback diagram (Exhibit 1). The remainder were grown, hulled and shelled, and processed by Paramount. Exhibit 2 contains a list of the Paramount finished product lot numbers sent to the Costco distribution center in Sumner, Washington, from September 2003 through February 2004 that contained almonds from outside suppliers.

A list of Paramount finished product lot numbers shipped in each purchase order was cross-referenced with a list of the almonds shipped from the Costco Distribution Center in Sumner, Washington (Exhibit 3) to various warehouse stores. This was compared to the case patient's almond purchase history. Using this information, a spreadsheet was generated showing the potential Paramount finished product lot numbers purchased by these patients. These lot numbers were traced back through the Paramount production chain (Exhibit 4). Analysis of the available data did not significantly decrease the number of contributing fields. As a result, no environmental investigation was conducted at the farm level. Environmental swabs were collected at Paramount by FDA investigators on two occasions, May 14, 2004 and May 25, 2004. Sampling sources were noted on the FDA Form 484 Receipt for Samples (Exhibit 5). [redacted] (Exhibit 6). Exhibit 7 contains a summary of all samples collected.

Facility Investigation: Paramount Farms, Inc., is a vertically integrated operation that includes the processing plant for almonds and pistachios, a hulling and shelling operation (Paramount Hulling and Shelling), and growing operations (Paramount Farming Company). Paramount Farms' processing company (Paramount) receives almonds from September through December, depending on the crop size and harvest dates. The firm processes nuts during the rest of that calendar year and continues into the next calendar year. The season would be designated by the harvest year, so product from the 2003 harvest would be processed into 2004.

All almonds received from PHS are received in wooden bins with disposable plastic liners (changed with each use) and cardboard covers. These bins each weigh approximately 2200-pounds when filled. Each bin is tracked with a barcode; the barcode is linked to the bin number and the PHS shipment lot number in the firm's product tracking database. The almonds are fumigated with Phostoxin (aluminum phosphide), which generates phosphine gas, for the purpose of controlling insects (Exhibit 8). The fumigation process takes a minimum of five days and may take longer under cold weather conditions. The concentration of phosphine gas must be less than four ppm before the bin can be opened safely. After fumigation is completed, the almonds remain in the covered bins out-of-doors until they are sent to pre-processing.

Pre-processing consists of a series of steps that remove debris and discolored almonds and then separate the almonds by size (Exhibit 9). Lot numbers are generated for each production schedule (in pre-processing a new schedule is created weekly). Multiple lot numbers from PHS are incorporated into each pre-processing lot. The sizer separates almonds into eight sizes. Product leaving pre-processing is packed in 2200-pound plastic lined wooden bins. Nut samples are collected at this point for the USDA inspector to verify grade by checking that they are clean, well dried, free from decay, rancidity, insect injury, foreign material, doubles, split or broken kernels, particles and dust, and free from damage caused by chipped and scratched kernels, mold, gum, shriveling, brown spot, and other means. There are seven USDA grades including: US Fancy, Extra No.1, No.1, Select Sheller Run, Standard Sheller Run, No.1 Whole and Broken, and No.1 Pieces. The graded and sized almonds are then sent to storage. Almonds packaged under the Kirkland label were labeled as US No.1 grade.

Almonds received from outside processors (Exhibit 10) are first sampled for USDA grade and then fumigated. No micro testing is required on purchases from outside vendors. From December through January, 88,000 pounds of purchased product was co-mingled with Paramount almonds under the Kirkland label. After fumigation is completed, these almonds go either to storage or directly to the laser sorter and from there, to production.

Although Paramount tracks all of the almonds placed in storage, they do not use a first-in, first-out system until the end of a harvest year. At that time, the oldest almonds might have been in storage for six or more months and the shelf life starts to become a factor (raw almonds have a two year shelf life at 60 percent Humidity and 75 degrees Fahrenheit). When they do begin to pick the oldest almonds out, the warehouse personnel must sort through bins to do so. During the majority of the year, almonds are pulled from storage by size and grade to fill the requirements on the schedule. Each of these orders consists of 56,000 pounds. Multiple pre-process and/or outside product lot numbers are used in each of these orders. No effort is made to minimize the number of lots incorporated into each order.

When the scheduler creates an order, product is pulled to fill the grade, size, and weight requirements for the order. The nuts are run through a hand-sorting line and the laser sorter. The hand-sorting line consists of four people on opposite sides of a conveyor. The first two people pull out foreign material and defects. The second two are inspectors who visually verify that the almonds meet the grade required. The almonds then go through the laser sorter. On leaving the laser sorter, the almonds are transferred into plastic lined, 2200-pound bins and receive a work-in-progress (WIP) code.

From the laser sorter, almonds go either to an additional hand sorting line in the manufacturing building or directly to packaging. In the case of raw almonds, most product goes directly to packaging. Raw almonds are packaged in a variety of sizes including 10-ounce bags, one-pound bags, three-pound bags and 25-pound bulk boxes. Bulk boxes can be packed on the hand sorting line located in the manufacturing building or on the bulk packaging line in the packaging area. Almonds in bulk are packed in unlined cardboard boxes or in unsealed plastic bags in cardboard boxes. All finished product receives a lot code.

After packaging, almonds are moved to the cold storage unit (unless they are to be shipped within the week in which case they go directly to the shipping dock). The firm maintains the cold storage at approximately 43 degrees Fahrenheit (confirmed on May 14, 2004 by FDB investigators using an Atkins Series 330 Thermocouple). Some customers, including Costco,

pick up product at Paramount. The truck brokerage firm Riolo is used for shipping to other customers.

Product Tracking: Almonds are received from the field in bottom dump trailers. As the product enters the pre-cleaner, information on the originating field, the time the product was entered into the pre-cleaner, and the weight of the load is entered into a tracking database. Because almonds move through the hulling and shelling process at varying speeds, there is co-mingling of loads in the huller/sheller. When "brown" almonds exit the huller/sheller, they are packed in 2200-pound, plastic lined bins. These bins are numbered and affixed with a bar code. The bar code is correlated with the number in the tracking database along with the time that the bin was filled. For the purposes of tracking one of these bins back to a field, PHS approximates the time for an almond to travel through the huller/sheller as two hours. From the huller/sheller, these bins are transported to Paramount Processing. There the almonds retain the same number until they enter pre-processing, where they are co-mingled with other almonds. In pre-processing, all almonds run in a one-week time period are assigned a single lot number. The bins incorporated into each pre-processing lot are recorded in the database. After the pre-processing stage, the almonds are sent to storage. When a purchase order is received, almonds are pulled from storage by size and grade and sent through the laser sorter where they are co-mingled with other pre-processing lots and sometimes with purchased almonds into one WIP code. Paramount does not have a first-in, first-out policy in place for stored product. This leads to the co-mingling of multiple pre-processing lots in each WIP code and also results in the converse; each pre-processing lot is divided and incorporated into numerous WIP codes. When almonds are packaged, each package is labeled with a coded lot number that reflects the date, production schedule number, and the shift number of packaging. Multiple finished product lot codes result from each WIP code. All of this data is tracked in Paramount's database. In the case of almonds sent to Costco in 2003-2004, between two and ten finished product lot numbers were combined in each purchase order. Paramount's database contained the lot codes shipped in each purchase order, but the Costco distribution center only tracked the purchase order number.

Product Testing: Paramount does not conduct routine testing of incoming almonds or finished products. Some of Paramount's customers do require finished product testing. In these cases, the customer determines the allowable limits. On customer request, finished product may be tested for *E. coli*, coliform, *Staphylococcus aureus*, *Salmonella*, yeast/mold, and total plate count (TPC). All tests are done in-house. A typical sample size is three-pounds per lot (lots range up to 150,000 pounds). If a product test revealed unacceptable microbial presence, Paramount would send that product to propylene oxide treatment, according to the firm. *Salmonella* test results for 2003-2004 were provided. No *Salmonella* was detected in these tests (Exhibit 11). Costco did not require finished product testing.

Sanitation: Sanitation occurs on a nightly basis. In pre-processing, sweeping and dusting is done frequently during operation. Nightly, all surfaces are blown down with compressed air.

In building 48 (manufacturing/hand sorting), there is a third shift (11 PM – 7:30 AM) responsible for sanitation. The sanitizer used was Quat Guard until February of 2004 when they changed to Sanitee 10 (Exhibit 12). Both sanitizers were prepared at a concentration of 200 ppm by diluting one-quarter ounce to 1 gallon of solution. Forklifts are not sanitized and they move freely between buildings.

In the packaging building (referred to as P-19), the operators also perform the duties of a cleaning crew (four or five employees per crew). The operators are responsible for cleaning

the packing line between product types or at least once a week. Almonds and pistachios are processed on the same equipment, so cleaning is done between species to minimize the opportunity for cross-contamination. Employees follow an equipment-specific sanitation checklist (Exhibit 13) and use a rag moistened with Windex or similar degreaser for cleaning. These rags are machine washed between each use. No sanitizer is used in the packaging building. During the peak period (September – January) packaging operations run 20 hours a day.

There are also specific weekly, monthly, and season-end sanitation requirements. The season end sanitation includes a full tear down, cleaning, and maintenance. Paramount conducts routine environmental sampling to verify sanitation efficacy. The firm has identified 62 food contact surfaces as sampling points (Exhibit 14). On average, ten samples are taken per week and all 62 points are covered every six weeks. All samples are screened for TPC. Half of the samples are screened for *Salmonella* via AOAC method 996.08 (May 1996). All tests are conducted by Paramount's in-house lab. At the time of the investigation, Paramount had no set action level for TPC. Review of records revealed that the last positive for *Salmonella* was found in October 2002. The sample was not serotyped. The firm's procedure following a *Salmonella*-positive is to notify the department overseeing the cleaning in that area and have them do a complete cleaning of the area, followed by repeat testing.

Employee Hygiene: Hand sanitizers are on the walls in the hand sorting room. Employees are required to attend a yearly safety training that includes a half-hour session on Good Manufacturing Practices (GMPs). Supervisors are expected to provide additional on-the-job training in GMPs as well.

Pest Control: Pest control is done in-house. Alex Ramirez is the fumigation manager for Paramount processing and PHS. Rodent bait stations and insect pheromone traps are used. Mr. Ramirez said that rodent bait stations are checked twice every month. They are placed at the exterior of all buildings and around the interior of the fenceline. Inside the buildings the firm has Ketch-all mechanical mousetraps at 25-foot intervals. These are checked once a week.

Paramount Hulling and Shelling
15853 Brown Material Road, Lost Hills, CA 93249-9719. Phone (661) 797-6808
Contacts: Tom Schwartz – Almond Hulling Operations Manager
Shawn Tremain – Senior Process Engineer

Traceback Investigation: The majority of almonds processed and sold by Paramount Farms are received from Paramount Hulling and Shelling (PHS). The hulling and shelling facility used for the 2003 season was newly built. It is located eight miles from the processing facility. On May 25, 2004 environmental sampling was conducted at PHS. A swab collected below huller module #1 was positive for *Salmonella* Quiniella, another taken from an LMC spout (feeding a bucket elevator) was positive for SE PT30.

Process Flow: Product is moved from the fields to the huller in bottom-dump trailers. The almonds are dumped through a metal grate into a pit. From the pit, the almonds move through the pre-cleaner, which is located in a shed (open on three sides) attached to the huller/sheller facility, then enter the storage tanks, which are inside the facility. The almonds then run through the hulling decks followed by the shelling decks as illustrated in the PHS Almond Huller Flow Plan (Exhibit 15) then go to the filler. The majority of the almonds are packed in 2200-pound, plastic lined bins. In 2003, PHS sold some almonds to Blue Diamond (mostly

from November – December). In order to do so, they altered their final filler to include an alternate conveyor that ran through a hole in the plant wall and dumped almonds into bottom hopper Blue Diamond trucks.

Transportation: Nuts are transported from the field to PHS in bottom-dump trailers rented from Standard Trailer Subs (Exhibit 16). These trailers were rented for the entire season. Many of the trailers were rented to other almond harvesters and contract trucking companies during the 2002 almond harvest. Representatives of these firms told investigators that the trailers were only used for almond hauling during the 2002 harvest. Nuts are transported to the Paramount Processing facility in wooden bins (plastic liner and cardboard cap) on flatbed trailers rented from Standard Trailer Subs. Semi tractors are contracted from Stevens Transportation.

Sanitation: Shawn Tremain, Senior Process Engineer is in charge of sanitation at PHS. Floors are swept and equipment blown down daily. Belts are taken outside and pressure washed twice a month. Twice monthly food contact equipment is sprayed with Sano Quat II, a quaternary ammonia sanitizer, and then rinsed. Sano Quat II is used at two ounces per four gallons of water. This is followed by swab testing of four points for TPC. The firm reported that 20,000 is an unofficial action level for TPC results. Walls are blown down daily and dry-wiped at the end of the season, according to Mr. Tremain. No cleaning procedures are in place for the bottom-dump trailers and they do not require the supplier (Standard Trailer) to clean them.

Maintenance: Equipment is maintained on a daily basis. No major changes have occurred since the facility first opened in 2003. The huller was closed from the last week of October through the first half of November to increase the size of one of the hoppers.

Pest Control: Mr. Alex Ramirez is the pest control manager for both Paramount's processing facility and the hulling and shelling facility. Mr. Ramirez said that the same pest control procedures are followed at both locations. At PHS, they also have bird traps that are monitored every two weeks. There is no log sheet for this check. Foil tape is strung on catwalks to discourage birds.

Sampling: Environmental swabs were collected by FDA investigators at PHS on two occasions, May 14, 2004 and May 25, 2004. On May 14, 2004, FDA investigators collected [redacted] environmental swab samples at PHS. [redacted]. On May 25, 2004, FDA investigators collected [redacted] environmental swab samples at PHS. Sampling sources were noted on the FDA Form 484 Receipt for Samples (Exhibit 5). [redacted]

Paramount Farming Company
33141 E. Lerdo Highway, Bakersfield, CA 93308 Phone 661-399-4456
Contacts: Joseph MacIlvaine – President

Paramount's almond fields are subdivided into four divisions, West Valley, Belridge, Dudley, and Eastside, all under the Paramount Farming central management structure (Exhibit 17). Eastside is located just west of CA-99, between Sherwood Avenue and Stockdale Highway. The remaining three divisions are located west of I-5, between Avenue 56/Ducort Highway and 7th Standard Road. These four divisions all follow the same farming practices as determined by the corporate office, with slight variations due to environmental factors such as rainfall and orchard age.

The four divisions are split into ranches that range in size from 80-2000 acres. Ranches are groups of trees all planted at the same time. Two to three varieties of almonds are grown in each orchard to ensure cross-pollination. Almond ranches are referred to by a four digit number that starts with the number three, followed by a sequential two digit number, and then zero. An example would be the Eastside 3010 ranch. When Paramount Farming runs test plots, they use two digits added sequentially to the end of the ranch number, for example 301001, 301002, etc. The ranches are split into blocks that are generally one-quarter section (160 acres). There is no naming convention for the blocks. They receive either a number or some combination of a number, a letter, and/or a dash. Fields are planted [redacted] trees to the acre. Paramount plants orchards with [redacted] trees per row and [redacted] feet between rows. A total of [redacted] tree/acres (equivalent of acres planted with a single variety) are planted in non-pareil almonds.

Water for the Eastside division comes from a mixture of the Kern River, wells, the California Aqueduct, and the Friant-Kern Canal. The other three divisions rely solely on the California Aqueduct for water. Irrigation is accomplished by a mixture of fanjet (micro-sprinklers), drip, and subsurface drip irrigation systems. Belridge and Eastside have a mixture of all three types, Westside uses only fanjets, and Dudley Ridge uses both fanjets and standard drip. Each block has an irrigation water reservoir with a set of auto-flushing sand-media filters. Irrigation water, whatever its source, is pumped into these reservoirs. The reservoir generally provides water for 24 hours to a third of a block at one time and cycles through until the entire block has been irrigated over the course of three days. During the winter months, the fields may only receive one 24-hour irrigation cycle per month. In the summer months, the system is continuously cycling so that each field is getting a full 24-hour irrigation cycle every three days. Irrigation is terminated seven to ten days before harvesting and usually doesn't resume until after the almonds have been collected. The timing is critical for these operations because it is important that the almonds are properly dried in the field, but it is also important that the trees not be water-stressed, as that will affect the following years yield.

Normally, two varieties of almonds are planted in each field to ensure maximum pollination. Non-pareils are grown with Carmel, Monterey, Butte, Sonora, Price, Fritz, Ne Plus, and Wood Colony varieties. Non-pareils are an early blooming variety and are generally harvested first. Bees are introduced in February to aid with pollination (two hives per acre). Orchard life is estimated at approximately 30 years. Paramount Non-pareil orchards range in age from five to 16 years old. Orchards are harvested after the third year. Harvest begins with a mechanical shaker that shakes each tree. The almonds fall onto the ground where they are allowed to dry. A sweeper then travels along the rows and rakes the almonds into a central windrow. A blower at the rear of the sweeper blows any almonds missed into an adjacent upswept row. This generates a large amount of dust and particulate matter. A mechanical harvester then travels down the row and transfers the nut into a reservoir cart. As the nuts are being collected, a shuttle vehicle can empty the reservoir cart and transfer the nuts to an elevator stationed at the perimeter of the field. This elevator transfers the nuts into a bottom-dump trailer. The nuts then go either to the huller/sheller or else to a field storage location where they are placed in piles, covered with tarps, and fumigated. Moisture content of the almonds is monitored in the field. If the nuts or hulls contain too much moisture when transferred to field storage, the piles can begin to generate heat.

The soil types in the Belridge Division are loams and sandy loams. The pH ranges from 7.2 – 8.0, and the electrical conductivities are from 1.0 – 2.0 milliSiemens per meter (mS/m). In the West Valley Division, soils types are loams to silty loams. The pH ranges from 7.2 – 8.0 and the electrical conductivities are from 0.5 – 2.0 mS/m. In the Dudley Ridge Division, soil types

are silty loams and clay loams. The pH ranges from 7.2 – 8.0 and the electrical conductivities are from 0.5 – 2.0 mS/m. The Eastside division soil is sandy loam. The pH ranges from 6.0 – 8.0 and the electrical conductivities are 0.3 – 2.0 mS/m.

Mr. MacIlvaine stated that they do not use, nor have they ever used compost, manure, or biosolids on any of their fields. The majority of the Paramount orchard properties were purchased in 1987. The Belridge properties were purchased later but have still been under Paramount control for at least ten years. Chemical fertilizers are applied to the orchards through the irrigation systems. Pesticides, miticides, fungicides, and herbicides are applied using sprayers pulled by tractor. When dilution is required, the water used is the same as the irrigation water. Weeds are controlled in the orchards by mowing and application of herbicides. The ground between rows is never tilled in order to maintain a smooth surface for almond collection operations. After each harvest, an iron bar is dragged along each row. This serves to prevent the dirt blown towards the center of each row during the harvesting operation from eventually forming into a hump.

Most equipment used in the orchards is owned by Paramount and is serviced and stored in their equipment yards. Some sweepers and harvesters and all of the bottom-dump trailers are rented. Equipment owned by Paramount is steam cleaned at the time of any major service but is never sanitized.

Mr. MacIlvaine said that there are no farm animals housed near any of Paramount's almond orchards. He reported the following wild animals have been seen in the orchards: bear (1x/year), mountain lion (1x/year), coyotes, rabbits, squirrels, weasels, snakes, gophers, mice, raccoons, skunks, cats/dogs, possums, frogs, kit foxes, kangaroo rats, red foxes, birds (multiple types). Employees on quadrunners patrol the orchards every morning (200 acres per person), primarily to monitor and repair the irrigation systems that are often damaged by pests.

Other Environmental Investigations & Tracebacks

Due to limited resources, FDB was unable to conduct environmental investigations at every processor and huller/sheller that supplied almonds to Paramount during the 2003-2004 almond-processing season. The decision to inspect and conduct sampling at these outside firms was guided by specific information. Sampling sources were noted on DHS-FDB Laboratory Analysis Request (LAR) forms (Exhibit 18).

Three fields, farmed by Baker, Hansen, and Lara (BHL), were implicated in the 2001 almond outbreak. As there was reason to believe that the 2004 outbreak strain was similar to the 2001 outbreak strain, priority was assigned to a traceforward investigation of almonds from the BHL fields. These almonds were hulled and shelled by West Valley Hulling and Shelling in 2003, then sent to Panoche Creek Packing, who had them blanched according to an agreement with CDHS.

A separate line of investigation followed from an FDA traceback of a patient who reported recurrent almond purchases from both Wal-Mart and Kroger stores (the specific dates of purchase were not known). Wal-Mart received almonds from Harrell Nut. Investigators learned that Harrell Nut treated all of the nuts sent to Wal-Mart with propylene oxide. Kroger received almonds from Poindexter Nut. Mr. Mike Poindexter, the sales manager for Poindexter Nut, told investigators that all almonds shipped to the Kroger Distribution Center in Atlanta were from two California suppliers, Minturn Nut Company and Harris-Woolfe Nut Company. It was not possible to determine which of these firms might have supplied the

almonds purchased by the case patient. The shipments from these suppliers were traced back as well (Exhibit 1). Investigation and environmental testing was conducted at Minturn Nut Co, Holland Nut Company, Minturn Coop Huller Sheller, Almond Tree Hulling, Farmers Coop Hulling, and CCAGA Hulling. The environmental samples did not detect the outbreak strain of *Salmonella*. [redacted], and *Salmonella* ser. Oranienburg was detected on the intake pit grate at CCAGA Hulling. The pit grate is the point at which in-hull almonds, with accompanying soil and debris, enter the facility.

Panoche Creek Packing
43940 North Avenue, Firebaugh, CA 93622 Phone (559) 659-4927
Contacts: Tom Tillery – Plant Manager
Site Visit: May 19, 2004

Traceback Investigation: Panoche Creek Packing is a custom packer located in Firebaugh. The investigation at Panoche Creek revealed that the majority of the shipments to Paramount were processed and shipped from Madera Almond Processing. Madera Almond Processing is partially owned by Ross Blackburn who is the sole owner of Panoche Creek Packing. On May 19, 2004, a joint ERU/FDA team collected eleven environmental swab samples at Panoche Creek Packing. Sampling sources were noted on the LAR forms (Exhibit 18). The samples were collected aseptically using Solar Biologicals, Inc. sponges (Lot #ALO3-5025 Exp. May 1/2005). One swab collected from a vibrator tray under an infeed hopper and another collected from a discard bucket tested [redacted] (Exhibit 7). [redacted]

Facility Information: The firm's hand-sorting equipment is wiped with a household bleach solution (1 tablespoon bleach/1 gallon water or approximately 50 ppm) on a daily basis. On a weekly basis, the employees wipe out all hoppers and food contact surfaces with a bleach solution of the same concentration. The firm maintains its own pest control program, which includes bait stations around the exterior of the facility and both glue traps and tin cats inside the facility. No monitoring records were provided. Panoche Creek only conducts microbiological testing on product at the request of a customer. On May 14, 2004, the firm collected four environmental swabs in its facility. These were sent to BSK Labs in Fresno and were negative for *Salmonella* (Exhibit 19).

West Valley Hulling Company
45475 West Panoche Road, Firebaugh, CA 93622 Phone (559) 659-7735
Contacts: Joe Areias – General Manager
Site Visit: May 20, 2004

Traceback Investigation: West Valley Hulling Company (West Valley) is an almond hulling and shelling company. West Valley hulls and shells all of the almonds harvested from the BHL farms implicated in the 2001 almond outbreak. On May 20, 2004, ERU staff collected eight environmental swab samples at West Valley. Sampling sources were noted on the LAR forms (Exhibit 18). The samples were collected aseptically using Solar Biologicals, Inc. sponges (Lot #ALO3-5025 Exp. May 1/2005). One swab collected from a sheer-roller tested [redacted] (Exhibit 7).

Facility Information: West Valley uses a high-pressure washer to clean equipment during the preseason sanitation (Exhibit 20). On a daily basis, West Valley uses compressed air to clean processing equipment in conjunction with sweeping. They vacuum where necessary. After

BHL runs, the firm follows its standard procedure to remove dust and then mists a solution containing 3M Brand Product 5H quaternary ammonia sanitizer (one-half ounce added per gallon of water) onto the food-contact surfaces. This solution is allowed to dry on the equipment. Exhibit 21 contains the manufacturers specifications and MSDS for this sanitizer. West Valley maintains an "Equipment Sanitation Log" (Exhibit 22). West Valley contracts with Clark Pest Control to install and monitor tin cats inside the plant and bait stations around the exterior of the building (Exhibit 23). The firm conducted environmental testing for *Salmonella* after every post-BHL plant sanitation (Exhibit 24). In September 2003, two of thirteen swabs tested were positive for *Salmonella* and in December 2003, one of thirteen swabs was positive for *Salmonella* (Exhibit 25). On both occasions, raw almonds were distributed prior to the firm receiving the results. West Valley notified each handler by fax (Exhibit 26) of their findings, yet did not recommend further treatment of the almonds as instructed previously by CDHS.

Madera Almond Processing, LLC.
21888 Ave 14, Madera 93637 Phone (559) 675-1900
Contacts: Denis Prosperi – Owner
Site Visit: May 25, 2004; June 9, 2004

Madera Almond Processing is a custom almond packer for Panoche Creek packing. Madera Almond Processing supplied multiple loads of almonds to Paramount during the 2003 almond season under the Panoche Creek name (Exhibit 10). The facility is comprised of two warehouses, each consisting of a roof enclosed on three sides, with the open side facing towards the processing (hand-sorting) building in the center. On May 25, 2004, environmental swab samples and product samples were collected at Madera Almond Processing by FDA investigators. The almonds sampled were from Ranch 20-1 Shop (almonds hulled and shelled at West Valley, manifest 12385). Invoices revealed that almonds from this ranch were also sent to Paramount. The sampled product was [redacted] (Exhibit 7).

Facility Information: Dust is blown off of the processing equipment twice a week with compressed air. The filter in the HVAC return in the hand-sorting room is replaced weekly. On a weekly basis, the hand-sorting belts are wiped with Quad 10, a quaternary ammonia based sanitizer (one ounce of Quad 10 added per gallon of water). Exhibit 27 contains the MSDS and label directions for this sanitizer. The bucket elevators are sprayed with the same disinfectant. Every two months, the bucket elevators are completely torn down and the buckets are scrubbed with a brush, soap and water, followed by a rinse. The buckets are then allowed to dry and then the bucket elevators are reassembled. Pest control for the plant is done in-house. No monitoring records were available. Glue traps were observed around the inside perimeter of the warehouse storage. Three mice were observed in one of these traps during one of our inspections. More than 50 bird droppings were observed in the two warehouse storage facilities. Mice and bird droppings were observed on top of the plastic liners of 2200-pound bins holding raw almonds. Holes were observed in these plastic liners. Mr. Denis Prosperi said that employees created these holes in order to take samples of the almonds in the bins. Madera Almond does not conduct routine environmental or product testing. Mr. Prosperi collected six environmental swabs on May 18, 2004. These swabs were sent to BSK labs where no *Salmonella* was detected (Exhibit 28).

Minturn Nut Company, Inc.
8800 S. Minturn Rd., Le Grand 95333-9711 Phone (559) 665-8500
Contacts: Rob Adams – Plant Manager

Roy Martinez – Quality Assurance Director
Susan Vizcarra – Shipping Manager
Site Visit: July 19, 2004

Minturn Nut Company (Minturn Nut) sizes and hand-sorts almonds for bulk sale. On July 19, 2004, ERU staff collected seven environmental swab samples at Minturn Nut. Sampling sources were noted on the LAR forms (Exhibit 18). The samples were collected aseptically using Solar Biologicals, Inc. sponges (Lot #AHO3-0225 Exp. Feb 1/2005). [redacted] (Exhibit 7).

Facility Information: The processing facility is cleaned daily after the last shift. Each night, employees blow down all the equipment using compressed air. They then spray all food contact surfaces with Alpet-D2 (an isopropyl alcohol/quaternary ammonia sanitizer) and allow it to sit for a minimum of sixty seconds before they wipe it off with a towel. Alpet-D2 is applied undiluted as recommended in technical specifications provided by the manufacturer, Best Sanitizers, Inc. (Exhibit 29). Pick-out buckets are cleaned daily. Every April, the buckets from the bucket elevator are removed and allowed to soak in bleach (two gallons of household bleach in 150 gallons of water). Minturn contracts with Clark Pest Control for bi-monthly maintenance of their pest control program. The pest control program consists of exterior bait stations and interior tin cats (Exhibit 30). Minturn has identified six points in its process flow that all almonds must move past. These points are swabbed on a monthly basis and the swabs are tested for *Salmonella* by Silliker Labs in Modesto. These tests did not detect *Salmonella* (Exhibit 31).

Holland Nut Company
2725 S. Sycamore Ave, Kerman 93630 Phone (559) 846-9377
Contacts: George Holland - Owner
Site Visit: July 19, 2004

Holland Nut Company (Holland Nut) sizes and hand-sorts almonds for bulk sale**.** Almonds from Holland Nut went to both Paramount and to Kroger in Tennessee (Exhibit 1**)**. On July 19, 2004, ERU staff collected seven environmental swab samples at Holland Nut. Sampling sources were noted on the LAR forms (Exhibit 18). The samples were collected aseptically using Solar Biologicals, Inc. sponges (Lot #AHO3-0225 Exp. Feb 1/2005). [redacted] (Exhibit 7).

Facility Information: Each night, employees wipe down the tables with towels, sweep, and then spray the equipment with Alpet-D2 (an isopropyl alcohol/quaternary ammonia sanitizer) and allow it to dry on the surface. Alpet-D2 is applied undiluted as recommended in technical specifications provided by the manufacturer, Best Sanitizers, Inc. (Exhibit 29). On a monthly basis, the bucket elevator and sizer are blown down with compressed air, wiped with a towel, and then sprayed with Alpet-D2, which is allowed to dry on the surface. The firm maintains 26 glue traps around the inner perimeter of their building and six bait stations around the outer perimeter. During the 2003 season, Holland Nut received almonds from West Valley that were run on equipment that tested positive for *Salmonella*. On October 7, 2003, Holland Nut had BSK Labs in Fresno test this product and no *Salmonella* was found (Exhibit 32). The firm swabbed equipment and had BSK Labs test the swabs for *Salmonella* on two occasions, October 3, 2003 and October 9, 2003. These tests did not detect *Salmonella* (Exhibit 33).

Minturn Cooperative Huller
9080 S. Minturn Rd., Chowchilla 93610 Phone (559) 665-1185

Contacts: Jeff Hamilton – General Manager
Site Visit: July 26, 2004

Minturn Cooperative Huller (Minturn Coop) is an almond hulling and shelling company located in Chowchilla. Minturn Cooperative Huller consists of two fully functional hulling and shelling operations on the same property. On July 26, 2004, ERU staff collected ten environmental swab samples at Minturn Coop. Sampling sources were noted on the LAR forms (Exhibit 18). The samples were collected aseptically using Solar Biologicals, Inc. sponges (Lot #AHO3-0225 Exp. Feb 1/2005). No *Salmonella* was detected in any of these samples (Exhibit 7).

Facility Information: Each year, prior to the start of processing, the Minturn Coop staff steam clean the pre-cleaners then spray them with Alpet-D2 (an isopropyl alcohol/quaternary ammonia sanitizer) using a hand-sprayer. The sanitizer is allowed to dry on the equipment. Alpet-D2 is applied undiluted as recommended in technical specifications provided by the manufacturer, Best Sanitizers, Inc. (Exhibit 29). On a daily basis, the inside of each plant is blown down and the equipment is sprayed with undiluted Alpet-D2. Brent Whiteman Pest Control is contracted to monitor and maintain the tin cats and bait stations at the facility (Exhibit 34). The interior is monitored on a weekly basis from August through November and then bi-weekly from December through July. The exterior is monitored on a monthly basis throughout the year. The firm has identified eight points in the hulling/shelling process that all nuts must pass through. They swab food-contact surfaces in these locations bi-weekly and test for TPC and/or *Salmonella* (Exhibit 35). No *Salmonella* was detected in any of these samples. TPC levels ranged from less than ten per swab to 1,500,000 per swab. The goal for TPC is under 3000 and the action level is 50,000. When the action level is exceeded, the facility is cleaned and sanitized, then tested again.

Almond Tree Hulling
23175 Rd 16, Chowchilla, 93610 Phone (559) 674-0349
Contacts: Ron Leach – General Manager
Site Visit: July 26, 2004

Almond Tree Hulling (Almond Tree) is an almond hulling and shelling company located in Chowchilla. On July 26, 2004, ERU staff collected five environmental swab samples at Almond Tree. Sampling sources were noted on the LAR forms (Exhibit 18). The samples were collected aseptically using Solar Biologicals, Inc. sponges (Lot #AHO3-0225 Exp. Feb 1/2005). A swab collected from the intake pit grate and another from the shelling line were [redacted] (Exhibit 7).

Facility Information: Prior to starting the season, the entire plant is blown down with compressed air and then washed with a high-pressure washer and Zonk, a food grade cleaner (Exhibit 36). All accessible areas are then sprayed with 3M Brand Product 5H quaternary ammonia sanitizer (one-half ounce added per gallon of water). Exhibit 21 contains the manufacturers specifications and MSDS for this sanitizer. Cleaning activities are documented on a timeline (Exhibit 37). Pest control for the plant is under contract with Clark Pest Control. Clark employees maintain and service both exterior bait stations and interior tin cats (Exhibit 38). After the preseason cleaning and on five additional occasions during the season, environmental swabs were collected from ten food-contact surfaces and sent to Silliker labs for testing. Half were tested for *Salmonella* and the remainder for TPC. No *Salmonella* was detected and all TPC results were less than 50 (Exhibit 39).

Farmers Cooperative Almond Huller, Inc.
30773 Los Angeles St., Shafter 93263 Phone (661) 746-4231
Contacts: Ron Geis - Manager
Site Visit: August 2, 2004

Farmers Cooperative Almond Huller, Inc. (Farmers Coop) is an almond hulling and shelling company located in Shafter. On August 2, 2004, ERU staff collected eight environmental swab samples at Farmers Coop. Sampling sources were noted on the LAR forms (Exhibit 18) and an Evidence/Sample Receipt was issued to the firm (Exhibit 40). The samples were collected aseptically using Solar Biologicals, Inc. sponges (Lot #AZ04-4154-1 Exp. Jun 1/2006). No *Salmonella* was detected in any of these samples (Exhibit 7).

Facility Information: A flow diagram of the hulling and shelling operation was provided (Exhibit 41). Prior to the start of the season, the entire plant is blown down with compressed air. The debris is then swept up and discarded, and the equipment is misted with Alpet D2 (an isopropyl alcohol/quaternary ammonia sanitizer) using a backpack sprayer. The sanitizer is allowed to dry on the equipment. Alpet-D2 is applied undiluted as recommended in technical specifications provided by the manufacturer, Best Sanitizers, Inc. (Exhibit 29). Pest control for the plant is done in-house. Tin cats are located around the inner perimeter of the building (Exhibit 42). These are inspected weekly. All bird nests are eradicated as soon as they are discovered. Any bird droppings found are immediately cleaned. The firm performed environmental swab testing of food-contact surfaces on one occasion prior to starting the 2003 season and then on five additional occasions during the season. Swabs were tested for TPC and/or *Salmonella*. TPC results ranged from less than ten per swab to 150 per swab, *Salmonella* results were all negative (Exhibit 43).

Central California Almond Growers Association- Kerman
8325 S. Madera Ave, Kerman 93630 Phone (559) 846-5377
Contacts: Darin Lundquist - Manager
Site Visit: August 3, 2004

Central California Almond Growers Association (CCAGA) is an almond hulling and shelling operation. CCAGA operates two hulling and shelling facilities, one in Kerman and the other in Sanger. On August 3, 2004, ERU staff collected eight environmental swab samples at CCAGA. Sampling sources were noted on the LAR forms (Exhibit 18) and on an Evidence/Sample Receipt form (Exhibit 44). At the time of our visit, one of the two huller/sheller lines at the Kerman facility was in operation; the other had not yet been started for the year. FDB investigators collected environmental swab samples from the processing line that had not yet been started. The line was still covered with dust and the plastic parts were stained with almond oil. The samples were collected aseptically using Solar Biologicals, Inc. sponges (Lot #AZ04-4154-1 Exp. Jun 1/2006). One swab collected from the intake pit grate tested positive for *Salmonella* ser. Oranienberg (Exhibit 45).

Facility Information: CCAGA has a written Sanitation Standard Operating Procedure (SSOP) for its facility. The SSOP does not address the cleaning of the plant or equipment (Exhibit 46). Mr. Lundquist stated that sanitation for the facility consists of blowing the interior down with compressed air, sweeping and removing dust and debris. The firm does not use any sanitizer on its equipment. Pest control for the plant is conducted in-house. The firm uses tincats and plastic traps inside the facility and bait stations on the exterior. The results of bait station inspections are recorded on a log sheet (Exhibit 47). The firm conducted testing

for *Salmonella* and TPC in August and September of 2003. No *Salmonella* was detected and TPC results ranged from less than 100 per swab to 400 per swab (Exhibit 48).

Exhibits

1. Traceback diagram
2. Summary spreadsheet- Paramount lot numbers for Kirkland Almonds containing almonds from outside sources (non-Paramount Farming)
3. Costco almond distribution information
4. Summary spreadsheet- potential Paramount lot numbers purchased by case patients
5. FDA Form 484 "Receipt for Samples"
6. FDA Form 1551 "Report of Sample Analysis"
7. Almond investigation environmental sampling table
8. Paramount fumigation procedures
9. Paramount facility diagram and process flow diagram
10. Paramount Farms raw almond purchases
11. Raw almond COA's issued by Paramount Lab
12. Sanitizing agents used in Paramount Farms Building 48
13. Paramount packaging building sanitation checklists
14. Paramount "Environmental Sampling Log"(10-13-03 through 1-26-04)
15. PHS almond huller flow plan
16. Paramount bottom-dump trailer rental history
17. Paramount Farms ranch maps
18. DHS-FDB "Laboratory Analysis Request" forms
19. Panoche Creek in-house environmental samples
20. West Valley sanitation procedures
21. Technical specifications: 3M Brand Product 5H quaternary ammonia sanitizer
22. West Valley equipment sanitation log
23. West Valley pest control logs
24. West Valley environmental testing records
25. Spreadsheet- West Valley post-BHL run test results
26. West Valley post-BHL positive notification letters
27. Technical specifications: Quad 10 sanitizer
28. Madera Almond Processing in-house environmental sampling results
29. Technical specifications: Alpet-D2 sanitizer
30. Minturn Nut Company pest control diagram
31. Minturn Nut Company in-house environmental sampling results
32. Holland Nut product testing results
33. Holland Nut in-house environmental sampling results
34. Minturn Cooperative Huller pest control diagram
35. Minturn Cooperative Huller in-house environmental sampling results
36. MSDS - Zonk
37. Almond Tree Hulling cleaning timeline
38. Almond Tree Hulling pest control diagram
39. Almond Tree Hulling environmental testing records
40. CDHS-FDB Evidence/Sample Receipt issued to Farmers Cooperative Huller
41. Farmers Cooperative Huller process flow diagram
42. Farmers Cooperative Huller pest control diagram
43. Farmers Cooperative Huller environmental testing records
44. CDHS-FDB Evidence/Sample Receipt issued to Central California Almond Growers Association
45. DHS-MDL Form 446 (CCAGA Sample Results)

46. Central California Almond Growers Association SSOP
47. Central California Almond Growers Association bait station inspection log sheet
48. Central California Almond Growers Association environmental testing records

Recommendations

Growers:

1. All growers should implement Good Agricultural Practices (GAPs).
2. All growers should avoid the application of uncomposted manure, biosolids, and primary or secondary treated sewage effluent.
3. Inspect all field equipment and bottom-dump trailers for cleanliness, odors, obvious dirt or debris before use. Operators should be aware of prior loads carried in a transport vehicle and take this information into consideration when determining use of a vehicle. Clean and sanitize when necessary.

Huller/shellers:

1. All huller/shellers should register under the DHS-FDB Processed Food Registration program.
2. Adhere to federal GMPs.
3. Maintain written SSOPs. Blow-down with compressed air should be avoided when possible, because it spreads contaminants to other surfaces. Vacuuming is preferable.
4. Develop and implement an ongoing worker food safety-training program. Include hand-washing protocols for all workers on hand sorting lines and others who touch the product.
5. Develop and implement a system for accurately linking the source farm or field for almonds received with the immediate subsequent recipient of those almonds.
6. Develop and implement an organizational policy and plan of action to follow in the event a product recall or similar action becomes necessary.
7. Implement an effective pest control program (with monitoring logs that document pest activity).

Handlers/Processors:

1. All handlers/processors must register under the DHS-FDB Processed Food Registration program.
2. All handlers/processors should include a pathogen reduction/elimination step.
3. Create “clean zones” to prevent cross contamination between pre- and post-treated almonds. Take all steps necessary, including but not limited to cleaning and sanitizing equipment (e.g. forklifts) and/or using only dedicated equipment in the “clean zone”. Implement an aggressive environmental monitoring program to verify the efficacy of these steps.
4. Maintain written SSOP’s including effective cleaning and sanitizing processes for equipment. Blow-down with compressed air should be avoided when possible, because it spreads contaminants to other surfaces. Vacuuming is preferable.
5. Adhere to GMP’s.
6. Develop and implement an ongoing worker food safety-training program. Include hand-washing protocols for all workers on hand-sorting lines and others who touch the product. Ensure workers understand and actively avoid activities that could lead to cross contamination and adulteration of food.
7. Develop and implement a system for linking the immediate previous source of almonds received with the immediate subsequent recipient of those almonds.
8. Develop and implement an organizational policy and plan of action to follow in the event a product recall or similar action becomes necessary.

9. Implement an effective pest control program (with monitoring logs pest activity). Exclude all animals from areas where food is manufactured, packed, or held.

Contributing Factors

1. Contaminated food eaten raw.